EXHIBIT __

From: Mike Mapes <mrmapes@gmail.com>
Sent: Thursday, July 2, 2009 5:30 PM
To: John Schultz
Subject: Reports from recent reviews
Attachments: Review of Order Monitoring Program.docx; SUGGESTED CHANGES TO THE SOP.docx; Review of Tablet Plant09.docx

John,

Attached are the reports from the recent visits to the Huntsville facilities. Let me know if there were any problems with the attachments.

Have a great holiday weekend,

Mike

--
Michael Mapes
(703) 436-2622

Review of Order Monitoring Program
Qualitest Pharmaceuticals
130 Vintage Drive
Huntsville, Alabama 35811

June 18, 2009

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Standard Operating Procedure:

The Standard Operating Procedure (SOP) for Qualitest Pharmaceuticals (QT) is SOP # QT01017.00. The SOP creates the policies by which controlled substances are distributed directly to retail pharmacies and practitioners by QT. The SOP created the Direct Retail Pharmacy Controlled Substance Questionnaire, the Retail Pharmacy Verification Checklist, the Retail Pharmacy Review, the Order Release Request, the Suspicious Order Report, the Practitioner Questionnaire, the Practitioner Verification Checklist, and the Practitioner Review.

Documents Reviewed:

The following documents were reviewed and appeared to be completed appropriately, leaving no questions for follow up:

- Three Practitioner Questionnaires and Three Practitioner Verification Checklist
- Ten Order Release Requests
- Forty Two Direct Retail Pharmacy Controlled Substance Questionnaire and Retail Pharmacy Verification Checklists

The following documents were reviewed and resulted in further questions:

- Five Practitioner Questionnaires and Practitioner Verifications
- Eighteen Direct Retail Pharmacy Controlled Substance Questionnaires and Retail Pharmacy Verification Checklists.
- Fourteen Order Release Requests

Each of the documents that required further explanations or had further questions was discussed with Jeremy Tatum, Inside Sales Manager for QT.

The following are examples of the questions that were raised while reviewing the documents:

1. A retail pharmacy in Kansas reported they ship to Kansas and Oklahoma but stated that they are not licensed in OK.
2. A retail pharmacy verification checklist for a pharmacy in North Plate, NE the verifier did not answer questions 3 and 4. A retail pharmacy in Breaux Bridge, LA is registered with an exempt DEA registration that is only for use at Federal or State institutions, as noted on the copy of the

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DEA 223 that was attached to the form. It is not known if the pharmacy has other DEA registrations.

3. A retail pharmacy in Seagoville, TX is shown on the TX Board of Pharmacy (BOP) web site as being on probation, but there was no follow up or issues noted on the Retail Pharmacy Verification Checklist.
4. Several pharmacies did not have pictures or copies of licenses or registrations attached, as requested.
5. A retail pharmacy in Moberly, MO is shown on the MO Division of Professional Registration website as on probation for numerous violations including controlled substance recordkeeping violations. This fact was not noted on the retail pharmacy verification checklist or shown as a response that suggests further inquiry.
6. There were several instances where retail pharmacies listed the names and DEA numbers of doctors that were prescribing narcotics in their area, but the names and DEA numbers were not checked because QT is not selling hydrocodone or oxycodone products directly to retail pharmacies.
7. For a retail pharmacy in New Iberia, LA the pharmacy did not answer several questions and that fact was noted on the Pharmacy Verification Checklist, but the checklist left blank the question about further inquiry.
8. For a retail pharmacy in Vidor, TX, there was information on the TX BOP website that both the pharmacy and pharmacist were on probation. The website did not provide additional information. The retail pharmacy verification checklist failed to mention the probation for the pharmacy and the pharmacist and did not highlight that as an issue for further inquiry.
9. A practitioner in Knoxville, TN was purchasing quantities of phentermine from QT. The phentermine was all being sent to a single location, then sent to the other four locations of the clinic by the purchaser. This distribution from one practitioner to another practitioner or location is a violation of 21 CFR 1307.11.
10. A physician in Oklahoma City, OK did not answer the question in the practitioner questionnaire about the quantities of controlled substances dispensed during a month. That fact was noted on the practitioner verification checklist, but no follow up was evident.
11. There was a weight management facility in Charleston, SC that has three other locations in the Southeast United Stated. The Practitioner Verification Checklist notes that all meds should be shipped to the Charleston, SC location, a violation of 21 CFR 1307.11.
12. A practitioner in Rosemead, CA failed to answer several questions on the practitioner questionnaire and put drug names as the answer to the questions about which suppliers you currently use and intent to continue to use. The verification checklist stated that all of the questions had been answered and there were no responses that would suggest further inquiry.
13. An order release form for a weight loss clinic in GA approved an increase in limits to 24,000 dosage units of phentermine a month. The form advised that the drugs will all be shipped to a single location for the other three locations, a violation of 21 CFR 1307.11.

There were several order release request forms that were not completed with the requested information. The reason given for the increase in limit was simply for additional business. There

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may have been additional reasons, but the reasons were not documented on the order release forms.

Suspicious Order reporting to DEA:

All orders that are identified by Qualitest as suspicious require the completion of a QT01017.05, Suspicious Order Report. The report is filed in the office of the Qualitest Director of Compliance and faxed to the DEA Diversion Group Supervisor in the DEA office in Birmingham, Alabama.

The most recent suspicious order report was forwarded to DEA on October 7, 2008 and concerned a pharmacy in Houston, TX that ordered suspicious quantities of hydrocodone. This suspicious order was well documented with a letter to DEA and the fax confirmation sheet that shows the date and time that the document was transmitted to the DEA office in Birmingham, AL.

The review of Order Release Requests showed that many requests were made for quantities of drugs that were several times greater than the current limit set in the order monitoring system. In most of those instances, the size of the order was cut down and the order was approved to be released, with some increase to the limit in the Order Monitoring System. Although the original order requested a quantity of controlled substances that was larger than QT was willing to ship to the customer, no report of a suspicious order was sent to the DEA as required by 21 CFR 1301.74(b). Each Order Release Request that is rejected or modified by QT should be sent to DEA as a suspicious order. Sending these orders to DEA will document to DEA that QT is monitoring the orders on a continuing basis and is monitoring controlled substance orders in a reasonable manner.

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SUGGESTED CHANGES TO THE SOP:¶
QUALITEST PHARMACEUTICALS¶
130 Vintage Drive¶
Huntsville, AL 35811¶
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STANDARD OPERATING PROCEDURE¶
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CONTROLLED INVENTORY ORDERS REV 07
PAGE 1 OF 4 ¶
SOP#: QT01017.00¶
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TITLE: EXCESSIVE AND SUSPICIOUS ORDER REVIEW AND MAINTENANCE¶
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WRITTEN BY/DATE:
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APPROVED BY/DATE:
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INITIATOR: _____EFFECTIVE DATE: _____¶
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PURPOSE: To define the procedure for reviewing orders which contain suspicious or excessive quantities of controlled substances and the reporting of the suspicious orders to the Drug Enforcement Administration (DEA).¶
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SCOPE: This procedure applies to customer service representatives and outside sales representatives who prepare controlled substance customer orders for both new and established accounts.¶
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DEFINITIONS: N/A¶
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PROCEDURE:¶
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REVIEW OF NEW ACCOUNT INITIAL ORDERS¶
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The appropriate customer service representatives/sales representatives preparing to service new accounts ... [1]

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Page 3: [1] Deleted **Mike M** **7/2/2009 12:21:00 PM**

SUGGESTED CHANGES TO THE SOP:
QUALITEST PHARMACEUTICALS
130 Vintage Drive
Huntsville, AL 35811

STANDARD OPERATING PROCEDURE

CONTROLLED INVENTORY ORDERS REV 07 PAGE 1 OF 4
SOP#: QT01017.00

TITLE: EXCESSIVE AND SUSPICIOUS ORDER REVIEW AND MAINTENANCE

WRITTEN BY/DATE: _____

APPROVED BY/DATE: _____

INITIATOR: _____EFFECTIVE DATE: _____

PURPOSE: To define the procedure for reviewing orders which contain suspicious or excessive quantities of controlled substances and the reporting of the suspicious orders to the Drug Enforcement Administration (DEA).

SCOPE: This procedure applies to customer service representatives and outside sales representatives who prepare controlled substance customer orders for both new and established accounts.

DEFINITIONS: N/A

PROCEDURE:

REVIEW OF NEW ACCOUNT INITIAL ORDERS

The appropriate customer service representatives/sales representatives preparing to service new accounts requesting delivery of controlled substances shall complete the Direct Retail Pharmacy Controlled Substance Questionnaire (Form No. QT01017.01) and/or Practitioner Questionnaire (Form No. QT01017.06), Retail Pharmacy Verification Checklist (Form No. QT01017.02) and/or Practitioner Verification Checklist (Form No. QT01017.07) prior to printing the new customer's initial order.

A copy of the customer's current DEA registration certificate or a print out of the DEA website registrant profile shall be attached to the new customer initial order printout.

The new account's location shall be verified by the Pharmacy Permit from the account's relevant State Board of Pharmacy or physician's license from the State Board of Medical Examiners.

Once the new account information is complete, their DEA registration and location have been verified the appropriate customer service representative shall attach the required documentation to the printout of the initial order.

The Sales Manager shall approve new retail customers and their initial order containing controlled substances. The Vice President of Sales and/or the Vice President of National Accounts shall approve the new non-retail customers and their initial orders containing controlled substances.

Qualitest will not sell only hydrocodone/oxycodone to a new retail pharmacy customer or new physician's practice or clinic.

The approved initial order shall then be released for inventory picking and shipping.

The required documents completed in "A." of this section shall be maintained in both electronic (Computer) and hard copy individual customer files.

Initial orders that are not approved by the appropriate manager shall be flagged as suspicious or excessive. The inside Sales Manager/designee shall then alert the Qualitest Department Manager and DEA Compliance for determination of notification to the DEA.

The DEA shall be notified upon determination of suspicious order using Suspicious Order Report (Form # QT01017.05). Additional written follow-up shall be sent to DEA as deemed appropriate.

New customers shall be subject to this new account review every thirty (30) days for the first ninety (90) days.

REVIEW OF ESTABLISHED ACCOUNT ORDERS

After an initial order for a customer account has been shipped the customer may be considered an established account.

Orders exceeding 3,000 combined doses of any strength of Hydrocodone solid dose products; 1,000 combined doses of Oxycodone; 3,000 doses of Phentermine; 3,000 doses of

Alprazolam; 6,000 doses of Diazepam; 6,000 doses of Clonazepam; 12,000 doses of Carisoprodol; or 12,000 doses of Propoxyphene, either as a single order, or multiple orders within a thirty-one calendar day rolling period, shall be stopped from processing due to electronic order entry modifications. These orders shall be flagged, and must be manually reviewed and approved by the Sales Manager/designee or Qualitest Department Manager prior to release for shipment. An Order Release Request (Form No. QT01017.04) shall be completed and signed by appropriate management.

In addition a report shall be generated and reviewed by a customer service supervisor on a bi-weekly basis for all established retail accounts, to see if any such account has ordered more than 3,000 combined doses of Hydrocodone; 1,000 combined doses of Oxycodone ; 3,000 combined doses of Phentermine; 3,000 combined doses of Alprazolam; 6,000 combined doses of Diazepam; 6,000 combined doses of Clonazepam; 12,000 combined doses of Carisoprodol; or 12,000 combined doses of Propoxyphene within a thirty-one calendar day rolling period. A Retail Pharmacy Review Checklist (Form No. QT01017.03) and/or a Practitioner Review Checklist (Form No.QT01017.08) will be completed quarterly and additional reporting may be created to track other controlled substances for established accounts, if deemed necessary, to assist customer service representatives in the review of excessive and suspicious orders.

Any established account orders containing additional controlled substances (other than Hydrocodone, Phentermine, Carisoprodol, Alprazolam, Clonazepam and/or Propoxyphene) may also be flagged as suspicious or excessive by a customer service representative and shall be reviewed manually and agreed to by the Sales Manager or Qualitest Department Manager prior to processing.

Orders for established customer accounts that are not approved by the Sales Manager or Qualitest Department Manager shall be flagged as suspicious or excessive. The customer service department shall then alert Qualitest Department management and DEA Compliance.

Qualitest Department management and DEA compliance shall make a determination if the DEA should be contacted concerning any potential suspicious order.

The DEA shall be notified upon determination of suspicious order using Suspicious Order Report (Form # QT01017.05). Additional written follow-up shall be sent to DEA as deemed appropriate.

Qualitest Department Management, after due diligence, may modify the quantity limits and / or time periods for the automatic hold and review of specific individual retail customers.

Existing customers that have not made any scheduled drug purchases for six (6) consecutive months shall be subject to the review required for new accounts when placing a scheduled drug order.

END SOP REV07 10/08

REVISION HISTORY:

Revision 00- Creation of a new SOP
Revision 01- The Excessive and Suspicious Order Review SOP was rewritten to account for new procedures that have been put in place.
Revisions 02-The products, Carisoprodol and Propoxyphene Napsylate have been added to sections II., B., C., and D.
Revision 03- Section I., I. was added. Section II., G. was added.

Revision 04- Revision Section I., E. - The official titles of management were added as employees who may approve new customers and initial orders with controlled substances. Section I., F. was added.
Revision 05- The products, Diazepam and Clonazepam have been added to sections II., B., C., and D.
Revision 06- Oxycodone added for suspicious order monitoring, outside sales reps added for suspicious order monitoring, Forms QT01017.01 – QT01017.05 added.
Revision 07- Alprazolam has been added to sections II., B.,C., and D. Forms QT01017.06-QT 01017.08 added.

SUGGESTED CHANGES TO THE SOP:

QUALITEST PHARMACEUTICALS

130 Vintage Drive

Huntsville, AL 35811

STANDARD OPERATING PROCEDURE

CONTROLLED INVENTORY ORDERS REV 07 PAGE 1 OF 4

SOP#: QT01017.00

TITLE: EXCESSIVE AND SUSPICIOUS ORDER REVIEW AND MAINTENANCE

WRITTEN BY/DATE: _____

APPROVED BY/DATE: _____

INITIATOR: _____EFFECTIVE DATE: _____

PURPOSE: To define the procedure for reviewing orders which contain suspicious or excessive quantities of controlled substances and the reporting of the suspicious orders to the Drug Enforcement Administration (DEA).

SCOPE: This procedure applies to customer service representatives and outside sales representatives who prepare controlled substance customer orders for both new and established accounts.

DEFINITIONS: N/A

PROCEDURE:

I. REVIEW OF NEW ACCOUNT INITIAL ORDERS

A. The appropriate customer service representatives/sales representatives preparing to service new accounts requesting delivery of controlled substances shall complete the Direct Retail Pharmacy Controlled Substance Questionnaire (Form No. QT01017.01) and/or Practitioner Questionnaire (Form No. QT01017.06), Retail Pharmacy Verification Checklist (Form No. QT01017.02) and/or Practitioner Verification Checklist (Form No. QT01017.07) prior to printing the new customer's initial order.

B. A copy of the customer's current DEA registration certificate or a print out of the DEA website registrant profile shall be attached to the new customer initial order printout.

C. The new account's location shall be verified by the Pharmacy Permit from the account's relevant State Board of Pharmacy or physician's license from the State Board of Medical Examiners.

D. Once the new account information is complete, their DEA registration and location have been verified the appropriate customer service representative shall attach the required documentation to the printout of the initial order.

E. The Sales Manager shall approve new retail customers and their initial order containing controlled substances. The Vice President of Sales and/or the Vice

President of National Accounts shall approve the new non-retail customers and their initial orders containing controlled substances.

F. Qualitest will not sell hydrocodone or oxycodone to a retail pharmacy customer or physician's practice or clinic.
G. The approved initial order shall then be released for inventory picking and shipping.
H. The required documents completed in "A." of this section shall be maintained in both electronic (Computer) and hard copy individual customer files.
I. Initial orders that are not approved by the appropriate manager shall be flagged as suspicious or excessive. The inside Sales Manager/designee shall then alert the Qualitest Department Manager and Qualitest Director of Compliance for determination of notification to the DEA.
J. The DEA shall be notified upon determination of suspicious order using Suspicious Order Report (Form # QT01017.05). Additional written follow-up shall be sent to DEA as deemed appropriate. A file of the Suspicious Order Reports send to DEA shall be maintained by the Qualitest Director of Compliance.
K. New customers shall be subject to this new account review every thirty (30) days for the first ninety (90) days.

II. REVIEW OF ESTABLISHED ACCOUNT ORDERS

A. After an initial order for a customer account has been shipped the customer may be considered an established account.
B. Orders exceeding 3,000 doses of Phentermine; 3,000 doses of Alprazolam; 6,000 doses of Diazepam; 6,000 doses of Clonazepam; 12,000 doses of Carisoprodol; or 12,000 doses of Propoxyphene, either as a single order, or multiple orders within a thirty-one calendar day rolling period, shall be stopped from processing due to electronic order entry modifications, unless the limits for a specific customer have been increased using the Order Release Request process These orders shall be flagged, and must be manually reviewed and approved by the Sales Manager/designee or Qualitest Department Manager prior to release for shipment. An Order Release Request (Form No. QT01017.04) shall be completed and signed by appropriate management. In addition to filing the Order Release Requests in both the customer electronic and paper file, all Order Release Requests will be filed in a single electronic file.

C. In addition a report shall be generated and reviewed by a customer service supervisor and distributed to Vice President of Sales, the Field Sales Support Manager, and the Director of Compliance. The report will be created on a bi-weekly basis for all established retail accounts, to see if any such account has ordered more than 0 combined doses of Hydrocodone; 0 combined doses of Oxycodone ; 48,000 combined doses of Phentermine; 12,000 combined doses of Alprazolam; 18,000 combined doses of Diazepam; 18,000 combined doses of Clonazepam; 24,000 combined doses of Carisoprodol; or 24,000 combined doses of Propoxyphene within a thirty-one

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D. Any established account orders containing additional controlled substances (other than Hydrocodone, Phentermine, Carisoprodol, Alprazolam, Clonazepam and/or Propoxyphene) may also be flagged as suspicious or excessive by a customer service representative and shall be reviewed manually and agreed to by the Sales Manager or Qualitest Department Manager prior to processing.

E. Orders for established customer accounts that are not approved by the Sales Manager or Qualitest Department Manager shall be flagged as suspicious or excessive. The customer service department shall then alert Qualitest Department management and the Qualitest Director of Compliance.
F. Qualitest Department management and the Qualitest Director of Compliance shall make a determination if the DEA should be contacted concerning any potential suspicious order.
G. The DEA shall be notified upon determination of suspicious order using Suspicious Order Report (Form # QT01017.05). Additional written follow-up shall be sent to DEA as deemed appropriate.

H. Qualitest Department Management, after due diligence, may modify the quantity limits and / or time periods for the automatic hold and review of specific individual retail customers.
I. Existing customers that have not made any scheduled drug purchases for six (6) consecutive months shall be subject to the review required for new accounts when placing a scheduled drug order.

END SOP REV07 10/08

REVISION HISTORY:

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Qualitest Pharmaceuticals

130 Vintage Drive

Huntsville, Alabama 35811

Review of Tablet Plant

June 16 – June 18, 2009

Summary:

In October of 2008, Michael Mapes and Terrance Woodworth were retained by Qualitest Pharmaceuticals to review evaluate the compliance with DEA regulations at the Qualitest tablet manufacturing plant in Huntsville, Alabama.

The review resulted in a report dated October 31, 2008, which provided specific recommendations for improvement in many areas including pre-employment background investigations, periodic reinvestigations of current employees, drug testing for employment applicants, periodic drug tests for current employees, updates to the power of attorney for executing DEA 222's, changing alarm codes for those with access to the alarm system, changing combinations to the vaults and safes that contain controlled substances, updating inventories for controlled substances in the laboratories, establishing a schedule for the testing of alarm systems that protect the controlled substance vaults and cages, implementing changes to the key control system for keys to the manufacturing areas, placing locks on the drying ovens that are used to process controlled substances, changes to the log books in the laboratories to more accurately reflect the movement of the drugs within the laboratories, creating separate inventories for schedule II and schedule III – V controlled substances in the laboratories, and improving the system for taking the biennial inventories for the various DEA registrations held by Qualitest.

From June 15 to June 18, 2009, Michael Mapes met with various Qualitest employees and managers to determine if the changes that were suggested as a result of the October 2008 review had been implemented by Qualitest. In almost every instance, the changes were implemented and the improvements to the systems were made.

Each of the initial recommendations made in the October 31, 2008 report is listed below along with the changes that have been implemented:

1. **Background Investigations**

It was recommended that QPI/VPL seek clarification of the extent of the current background inquiries and that a system be implemented that provides for periodic reinvestigations of the backgrounds of all employees of QPI/VPL with access to controlled substances.

June 2009 Situation:
For new employees that are hired directly by QT, they check the FDA OIG website, the Madison County, AL Sheriff's Office, and the Birmingham, AL office of the Drug Enforcement Administration (DEA). The Madison County Sheriff's office check includes arrests, indictments, and convictions from most jurisdictions in the United States. This includes most of the office employees and professional employees such as chemists.

For new employees who are hired through a staffing agency the staffing agency utilizes the Clear Investigative Advantage system for background investigations. This system completes a nationwide criminal and civil check. When the employees start work at QT, a check is sent to the Madison County Sheriff's Office and to the DEA. It generally takes two weeks to receive a response from the Madison County Sheriff's Office and three to four weeks to receive a response from the DEA. While new employees may be working with controlled substances before the results of the background investigations are received, they are always supervised by a permanent employee who has had a completed background investigation.

There are no periodic reinvestigations of the backgrounds for employees at QT. If an employee who has been the subject of a background investigation is given unescorted access to controlled substance storage or manufacturing areas, the employees name and information is sent to the Birmingham, AL office of the DEA for a background check.

2. Employee Drug Testing

It was recommended that the drug testing of employees be expanded to include the drugs that are manufactured by QPI/VPL such as benzodiazepines, oxycodone, hydrocodone and propoxyphene.

June 2009:

The drug panel that is currently used by QPI/VPL for routine testing of employees includes opiates/morphine, amphetamine, methamphetamine, benzodiazepines, oxycodone, hydrocodone, and propoxyphene. Since the change was implemented, one employee was dismissed for failing the drug test. The employee admitted to ingesting a hydrocodone tablet.

3. Power of Attorney Forms

It was recommended that the Power of Attorney forms to execute DEA-222's be updates, as the forms being used were issued by an individual no longer employed by QPI/VPL.

June 2009:

The Power of Attorney forms to execute DEA-222's were updated and authorized by the new CEO of QPI/VPL. The updates were signed in June of 2009.

4. **Alarm System Access Codes**

It was recommended that the access codes for the alarm systems in each of the areas of the facilities that stored or processed controlled substances be changed.

June 2009

The alarm system access codes for all of the systems in each of the QPI/VPL facilities in Huntsville, AL have been changed within the past two months. The security department is planning on changing the codes on an annual basis.

5. **R&D Controlled Substances Stored in the Raw Materials Cage**

It was recommended that the inventory for the R&D samples that are stored in the raw materials controlled substance cage be conducted and that samples that were no longer required be destroyed in an appropriate manner.

June 2009

The R&D controlled substance samples that were stored in the controlled substances raw materials cage have been properly inventories and those samples that were ne longer needed have been destroyed.

6. **Doors on Cages and Vault Day Gate**

It was recommended that the practice of holding the cage door open with a cord when someone was working in the cage be discontinued. It was also recommended that the day gate in the vault be closed when the door of the vault is open and someone is working in the vault. The door and day gate may be held open only when driving a fork lift or pallet jack into the cage and when the door of the cage of vault is under direct supervision by someone with authorized access to the cage of vault.

June 2009

The practice is now that the cage door or the vault day gate are closed when someone is working within the cage or vault, except when moving material into or out of the cage or vault. When the door to the cage or vault are open, the area is under direct close supervision by one of the persons with authorized access to the area.

There have been some modifications to the structure of the cage since October of 2008. The DEA was advised of the modifications by the Qualitest Director of Compliance. In the area around the cage door, the new bolts that were put in place were not brazed so that they may not be dismantled as required by 21 CFR 1301.72 (b) (4) (i) (b).

7. Cage Motion Detectors

It was recommended that the motion detectors in the cage be tested routinely and calibrated to assure that no area of the cage was left unprotected by the motion detection system.

June 2009

The motion detection system in the cage has been recently tested and found to be operating security system and maintenance of the alarms. A change to the procedures should be documented to ensure that the alarm systems are tested and documented on a regular basis.

8. Inventories in the Laboratories

It was recommended that the log books that are maintained in both the Quality Control and the Research and Development Laboratories be updated to more closely track the movement of the controlled substances within the laboratories.

June 2009

A review of both the Quality Control and the Research and Development Laboratories showed that the log books have been changed and updated to properly record the movement of controlled substances.

9. The DEA Biennial Inventory

It was recommended that significant changes be made to the required DEA Biennial Inventory to more accurately reflect al of the controlled substances maintained in the various areas of Qualitest.

June 2009

A review of the Biennial Inventory that was completed after the October 2008 review showed that a new inventory was taken and the new inventory was a complete, accurate

reflection of the controlled substances that were maintained at the time of the inventory. QT obtained authorization from the DEA to use the new inventory as an official required inventory.

ACTION ITEMS:

1. Braise the bolts in the areas of new construction in the controlled substance raw materials and in-process goods cage in the tablet plant.
2. Change the combination to the door of the controlled substance vault in the tablet plant and establish a plan for changing the combination on an annual basis and documenting the changes.